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| 09/882,359      | 06/14/2001  | Shankar Subramaniam  | P-SH 4810           | 6705             |

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EXAMINER

WHISENANT, ETHAN C

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/882,359

**Applicant(s)**

SUBRAMANIAM

**Examiner**

Ethan Whisenant, Ph.D.

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

1. The applicant's Response (filed 25 MAR 03) to the Office Action has been entered. Following the response, **Claim(s) 1-36** is/are pending. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

### 35 USC § 112- 2ND PARAGRAPH

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

### CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

3. **Claim(s) 9, 21 and 33** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Claim(s) 9, 21 and 33** are indefinite because it is unclear what is intended. How can said pair of fragments (i.e. genomic fragments) have a portion of adjacent sequence compared to said genomic DNA? Please clarify.

Please note that in the prior art rejections which follow "a portion of adjacent sequence compared to said genomic DNA" is that portion of vector sequence which remains following PCR amplification, see p. 12 of Dale in the section entitled "Preparation of Genomic Array".

**35 USC § 102**

- 4.** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) The invention was described in --

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

**Claim Rejections under 35 USC § 102**

- 5.** Claim(s) 1-3, 5, 7-11, 13-15, 17, 19-23, 25-27, 29, 31-35 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Stephan et al. (MAY 2000).

Stephan et al. teach a method for determining a sequence boundary or a plurality of sequence boundaries which comprises all of the limitations recited in Claims 1-3, 5, 7-11, 13-15, 17, 19-23, 25-27, 29, 31-35. Note especially Part A of Figure 2. Note the identified intron/exon boundaries.

**35 USC § 103**

- 6.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim Rejections under 35 USC § 103**

**7. Claim(s) 4, 16, and 28** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Stephan et al. (MAY 2000).

Stephan et al. teach a method for determining a sequence boundary or a plurality of sequence boundaries which comprises all of the limitations recited in Claims 4, 16, and 28 except these authors do not explicitly teach using RNA as the target polynucleotide. However, it is well known in the art that cDNA (i.e. the target polynucleotide used by Stephan et al.) is simply the inverse complement of RNA. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use RNA instead of cDNA in the method of Stephan et al. The substitution of one known reagent with known properties for a second well known reagent with known properties is routine in the art. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their

**8. Claim(s) 12, 24, and 36** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Stephan et al. (MAY 2000).

Stephan et al. teach a method for determining a sequence boundary or a plurality of sequence boundaries which comprises all of the limitations recited in Claims 12, 24 and 36 except these authors do not explicitly teach using DNA fragments of at least 1000 bp. Rather, Stephan et al. teach that the arrayed genomic fragments were 500bp average length. However, absent an unexpected result, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention that one could with a reasonable expectation of success substitute 1000bp fragments for the 500bp fragments used by Stephan et al. The substitution of one known reagent with known properties for a second well known reagent with known properties is routine in the art. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their

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**9.** Claim(s) 6, 18, 30 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Stephan et al. (MAY 2000) as applied against Claims 1, 5, 13, 17, 25 and 29 above and further in view of Dale [US 6,562,569 (MAY 03)].

Stephan et al. teach a method for determining a sequence boundary or a plurality of sequence boundaries which comprises all of the limitations recited in Claims 6, 18 and 30 except these authors do not explicitly teach using particles as the surface to address fragments of eukaryotic DNA. Rather, Stephan et al. teach the use of glass slides as the solid support. However, Dale teaches having arrays on beads (i.e. particles) which allows for both the detection of specific nucleic acids and the isolation of the same nucleic acids. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Stephan et al. wherein beads are used as the solid support instead of glass slides in order to gain the advantages recited by Dale. See Dale Column 22, beginning at about line 45.

#### RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

**10.** Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are moot in view of the new ground(s) of rejection. It is noted however, that the rejection of Claims 1-36 under 35 USC 112, first paragraph is withdrawn in light of the applicant's persuasive argument(s).

#### CONCLUSION

**11.** Claim(s) 1-36 is/are rejected and/or objected to for the reason(s) set forth above.

**12.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

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The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.



**ETHAN WHISENANT**  
**PRIMARY EXAMINER**